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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, ex rel. CAMPIE, Plaintiff and Relators, v. GILEAD SCIENCES, INC., Defendant.	CASE NO. C-11-0941 EMC **UNITED STATES' MOTION TO DISMISS RELATORS' SECOND AMENDED COMPLAINT; [PROPOSED] ORDER** Date: June 20, 2019 Time: 1:30 p.m. The Honorable Edward M. Chen Courtroom 5, 17th Floor

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NOTICE OF MOTION AND MOTION TO DISMISS

PLEASE TAKE NOTICE THAT on June 20, 2019 at 1:30 p.m., or as soon thereafter as the matter may be heard by the Court, in the courtroom of the Honorable Edward M. Chen, located at 450 Golden Gate Avenue, San Francisco, California, Courtroom 5, real party in interest the United States of America will and hereby does move the Court, pursuant to 31 U.S.C. § 3730(c)(2)(A), for an order dismissing Relators' Second Amended Complaint.

The United States brings this motion on the grounds that it has a valid governmental purpose in dismissing the case, and that there is a rational relationship between dismissal and accomplishment of the purpose. This motion to dismiss constitutes a determination by the United States as a matter of its prosecutorial discretion that Relators' pursuit of this case is contrary to the United States' interests on whose behalf Relators are supposed to be pursuing the case.

The United States' motion is based on this Notice of Motion and Motion, the attached Memorandum of Points and Authorities, all pleadings and papers filed in this action, oral argument of counsel, and any other matters as may come before the Court.

MEMORANDUM OF POINTS AND AUTHORITIES

I. STATEMENT OF ISSUES TO BE DECIDED

Whether Relators' Second Amended Complaint should be dismissed where the United States, real party in interest, has moved for dismissal pursuant to 31 U.S.C. § 3730(c)(2)(A), and has shown a valid government purpose in dismissing the case and a rational relationship between dismissal and accomplishment of that purpose.

II. STATEMENT OF FACTS

A. Relators' Allegations

In October 2010, Relators Jeff Campie and Sherilyn Campie ("Relators") filed this *qui tam* action against defendant Gilead Sciences, Inc. (Gilead), a manufacturer of numerous prescription drugs. Although their Second Amended Complaint catalogues a lengthy list of allegations about a number of different products, Relators' key allegations concern alleged deficiencies in Gilead's manufacturing of certain pharmaceutical drugs. *See* ECF 126.

Relators allege that, in the course of manufacturing various pharmaceutical drugs approved by the Food and Drug Administration (FDA), Gilead covertly arranged to have certain key ingredients made at two manufacturing facilities (one in China and one in Canada) that had quality control problems. Relators allege that problematic ingredients produced at these facilities, as well as assorted problems at several other facilities, led to Gilead producing substantial quantities of drugs that were contaminated and/or did not have the proper potency levels. Relators further allege that, for at least part of the time that Gilead used these facilities, the facilities had not been approved by FDA to make pharmaceutical ingredients destined for the U.S. market but that Gilead nonetheless introduced the resulting drugs into U.S. commerce.

Relators also allege that Gilead took a number of steps to conceal these underlying problems. For example, the Second Amended Complaint states that when Gilead eventually sought FDA approval for the new Chinese facility (Synthetics China), it made false statements to FDA about quality testing results. Relators also contend that Gilead falsified shipping labels to conceal from FDA the fact that Gilead had been (and still was) using ingredients made at the unapproved Chinese facility. And Relators allege that in a variety of instances, Gilead either failed to file required reports with FDA noting problems with its drugs or made false representations or material omissions in applications seeking FDA's approval for various drugs.

Relators contend that Gilead violated the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, by causing the submission of false claims to federal health care programs. More specifically, Relators assert that Gilead's conduct gives rise to violations of the FCA because FDA would have denied or revoked the relevant drugs' approval had it known the truth, which in turn would have affected the drugs' eligibility for payment under federal health care programs.

B. The Government's Investigation

The government investigated Relators' allegations for over two years. Accompanying Declaration of Leonard Russo, ¶ 2.[1] The government reviewed Relators' complaint and amended complaint, their disclosure statement, and the accompanying materials. *Id.* The

[1] This case was originally filed in the Eastern District of Pennsylvania in August 2010 and transferred to this District in 2011.

government interviewed Relators. *Id.* The investigation included consultation with experts from the Department of Health and Human Services (HHS), including FDA. *Id.* The government met with counsel for Gilead on multiple occasions to discuss the allegations. *Id.* The government collected over 600,000 pages of documents related to the allegations and interviewed numerous witnesses. *Id.* The government also selected multiple manufacturing lots for which Relators had alleged specific and potentially serious problems and obtained a complete review of the history of the lots from "cradle to grave," which accounted for the disposition of each lot with supporting documentation. *Id.* at ¶ 3.

After thoroughly investigating and meaningfully assessing the Relators' allegations, in January 2013, the United States declined to intervene in the action, pursuant to 31 U.S.C. § 3730(b)(4)(B). Relators elected to proceed with the action and filed an amended complaint. Defendant Gilead moved to dismiss the amended complaint. ECF 58.[2] The United States filed a statement of interest in response to the motion to dismiss to set forth its position on the proper interpretation and application of certain legal issues raised by Gilead. The United States took no position on the merits of Relators' claims or whether the Relators' allegations were adequately pled. The Court granted Gilead's motion and dismissed the complaint, but granted Relators leave to amend. ECF 117. The Court instructed Relators to organize and streamline their 747-paragraph complaint and permitted them to allege a new theory of liability based on alleged "worthless services" and an actionable misrepresentation made as part of the payment process. *Id.* The Second Amended Complaint did not allege new conduct or alter the overall focus of the allegations, and did not change the government's view about its decision to decline to intervene in this matter. *See* ECF 126. Gilead moved to dismiss the Second Amended Complaint, and the United States again filed a statement of interest. ECF 128, 129. The Court dismissed the Second Amended Complaint, and Relators appealed. ECF 142, 145. The United States once again participated as an *amicus* in the briefing to inform the Ninth Circuit of its views on the legal issues raised by the appeal. The Ninth Circuit reversed this Court's dismissal of the action. ECF

[2] Some of the docket entries remain sealed, and therefore the docket numbers for certain entries are not included here.

150-51. After a petition for rehearing *en banc* was denied, defendants petitioned for certiorari to the United States Supreme Court. ECF 154, 162. The Supreme Court denied certiorari, and the case was remanded to this Court. ECF 166, 168.

C. FDA's Ongoing Regulatory Oversight

Before Relators disclosed their allegations to the government, FDA was already conducting ongoing regulatory oversight of Gilead's manufacturing processes. In 2008, Gilead submitted a Prior Approval Supplement (PAS) to allow the use of active pharmaceutical ingredients (API) from a new manufacturer (Synthetics China) in its finished drug products. Accompanying Declaration of George Scavdis, ¶ 2. In the PAS, Gilead committed to providing additional stability data when it became available. *Id.* In March 2009, FDA conducted an on-site inspection of Synthetics China. *Id.* As part of the inspection, Gilead disclosed that two validation batches of API did not meet the specifications in the drugs' label, but that changes were made to the process design and the validation was repeated and acceptable results were obtained. *Id.* At the conclusion of an inspection, FDA may issue a "Form 483" if the investigators observed violations of the FDCA. In this case, however, FDA did not issue a Form 483, having recorded no deficiencies with the manufacturing or testing operations at Synthetics China that warranted further regulatory action. *Id.* In April 2009, Gilead submitted a PAS amendment with additional stability data. *Id.* On May 8, 2009, FDA approved the PAS for Synthetics China. *Id.*

FDA's ongoing regulatory oversight continued after Relators filed their complaint and the government was aware of their allegations. Between January and February 2010, FDA had inspected a Gilead facility in San Dimas, California and identified certain violations of the Current Good Manufacturing Practice (cGMP) regulations. *Id.* at ¶ 3. FDA discussed its findings with Gilead. FDA issued a Warning Letter on September 21, 2010. *Id.* FDA evaluated the corrective actions that Gilead took in response to the Warning Letter, and on August 4, 2011, FDA issued a letter to Gilead stating that those corrective actions appeared to address the violations contained in the Warning Letter. *Id.* Meanwhile, in April 2011, FDA conducted a second on-site inspection of the Synthetics China facility. *Id.* at ¶ 4. FDA did not issue a Form

483 based on the April 2011 inspection. *Id.* Between November 2011 and January 2012, Gilead submitted Field Alert Reports to FDA related to particulates in finished product at the Foster City facility. *Id.* at ¶ 5. In June 2012, FDA inspected the Foster City facility and issued a Form 483 relating to cGMP deficiencies. *Id.* In March 2012, FDA requested additional information about validation and reprocessing of batches at Synthetics China, and received additional information from Gilead in April 2012. *Id.* at ¶ 6. In March 2013, FDA conducted a third on-site inspection of the Synthetics China facility. *Id.* FDA did not issue a Form 483 based on the March 2013 inspection. *Id.*

FDA did not initiate any action in response to these inspections that caused or required Gilead to stop production at any Gilead facility, recall any lots of the drugs at issue, or remove the drugs from commerce. *Id.* at ¶ 7.

III. STATEMENT OF LEGAL AUTHORITY

A. The False Claims Act

The FCA enables the United States to recover monies lost due to the submission of false claims. 31 U.S.C. § 3729. Among other unique features, the FCA allows private parties, known as relators, to bring an action on behalf of the United States through filing a *qui tam* action. A *qui tam* action is brought in the name of the United States, but a relator has a right to a share of up to thirty percent of the recovery, plus attorneys' fees and costs. 31 U.S.C. § 3730(b), (d).

The FCA directs that the relator must file his or her complaint under seal and serve it, together with a "written disclosure of substantially all material evidence and information the person possesses," upon the United States. 31 U.S.C. § 3730(b)(1), (2). The United States has at least 60 days to investigate the allegations and elect whether or not to intervene in the action, with extensions of time for good cause. 31 U.S.C. § 3730(b)(2), (3).

If the United States intervenes, "the action shall be conducted by the Government." 31 U.S.C. § 3730(b)(4)(A). The government assumes "the primary responsibility for prosecuting the action" and is not bound by any act of the relator. 31 U.S.C. § 3730(c)(1). The relator remains a party to the suit, but the government may settle the case over the relator's objection, or may otherwise seek to limit the relator's participation in the litigation. 31 U.S.C.

§ 3730(c)(2)(B), (C).

Even if the United States declines to intervene in the action, the government retains substantial control over the action. For example, the Court may stay discovery in the *qui tam* action if it interferes with the government's investigation or prosecution of another matter. 31 U.S.C. § 3730(c)(4). The relator cannot dismiss the action without written consent of the Attorney General. 31 U.S.C. § 3730(b)(1). And if the Attorney General initially declines to intervene in the suit, the court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. § 3730(c)(3).

Most important for purposes of the present motion, the FCA expressly authorizes the United States to dismiss the action over the relator's objection:

> The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

31 U.S.C. § 3730(c)(2)(A). The United States can move to dismiss a FCA action even though it did not intervene in the litigation, as it remains the real party in interest. *See United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (noting that § 3730(c)(2)(A) "may permit the government to dismiss a *qui tam* action without actually intervening in the case at all"); *Ridenour v. Kaiser-Hill Co., LLC*, 397 F.3d 925, 932 (10th Cir. 2005) (affirming dismissal after declination); *Swift v. United States*, 318 F.3d 250, 251-52 (D.C. Cir. 2003) (affirming dismissal prior to intervention); *cf. United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1215 (9th Cir. 1996) ("[*Q*]*ui tam* plaintiffs are merely agents suing on behalf of the government, which is always the real party in interest.") (citing cases).

B. The United States' Decision to Dismiss a *Qui Tam* Case is a Matter of Prosecutorial Discretion Entitled to Deference.

The Ninth Circuit, in *Sequoia Orange*, adopted a highly deferential standard of review for a government motion to dismiss a *qui tam* case pursuant to 31 U.S.C. § 3730(c)(2)(A). 151 F.3d at 1145. In order to dismiss a matter such as this, the United States need only (1) identify a "valid government purpose" for dismissing the case, and (2) show a "rational relationship between dismissal and accomplishment of the purpose." *Id.* (quotations omitted). If the United

States satisfies this two-step test, "the burden switches to the relator to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *Id*. (quotations omitted).

In developing this test, the Ninth Circuit observed that "the decision to dismiss has been likened to a matter within the government's prosecutorial discretion in enforcing federal laws," and the dismissal provision in the FCA should not be construed to grant the Judiciary an impermissible power to approve or disapprove the Executive's exercise of prosecutorial discretion. *Id*. at 1143. Consequently, the Ninth Circuit reasoned that when a court considers a motion by the government to dismiss a *qui tam* case, it should "respect[] the Executive Branch's prosecutorial authority by requiring no greater justification of the dismissal motion than is mandated by the Constitution itself." *Id*. at 1146. There are good reasons for this type of deference:

> First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.

Heckler v. Chaney, 470 U.S. 821, 831-32 (1985).

This Court has further elucidated its view of how to evaluate whether the government has met its burden and a relator has met his. *See United States ex rel. Thrower v. Acad. Mortg. Corp.*, No. 16-cv-2120, 2018 WL 1947760 (N.D. Cal. April 25, 2018). In *Thrower*, the Court explained that "to establish a colorable claim to obtain an evidentiary hearing on the Government's motion to dismiss, a relator must present 'some evidence' that the Government's decision to dismiss was unreasonable, not a result of a full investigation, or based on arbitrary and improper considerations." *Id.* at *4. Although the government does not entirely agree with this Court's interpretation and application in *Thrower* of the pertinent standard adopted by the Ninth Circuit in *Sequoia Orange* (and is currently appealing the *Thrower* decision), the United

States submits that its request for dismissal satisfies the test that this Court required in *Thrower*.

IV. DISCUSSION

In this matter, the government has a legitimate purpose for dismissal: to avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue. As noted above, in a *qui tam* action, the relator sues on behalf of the United States for fraud against the United States, and to recover damages suffered by the United States. Accordingly, even where the United States declines to intervene in a *qui tam* action, if the relator opts to pursue the case, the government's resources often are still burdened, as relators may litigate FCA cases long after the government has determined that the alleged violations do not warrant further action. Such has already been the case here.

The goal of minimizing expenses and government resources is "a legitimate objective, and dismissal of [a] suit is furthered by that objective." *Swift*, 318 F.3d at 254; *see Sequoia Orange*, 151 F.3d at 1146 ("[T]he government can legitimately consider the burden imposed on taxpayers by its litigation, and that, even if the relators were to litigate the FCA claims, the government would continue to incur enormous internal staff costs. . . ."); *cf. United States ex rel. California v. Washington Twp. Health Care Dist.*, No. 06-cv-00261, 2006 WL 2053494 (N.D. Cal. July 21, 2006) (noting, in context of relator's voluntary motion to dismiss *qui tam* suit, that "consideration of cost" is a "sufficient justification to approve dismissal" of action). The Supreme Court has observed that an agency's decision not to enforce "often involves a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," including "whether agency resources are best spent on this violation or another." *Heckler*, 470 U.S. at 831. As a result, such determinations are "general[ly] unsuitab[le] for judicial review" because "[t]he agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831–32.

In this case, the government fully investigated Relators' allegations, including all information provided by Relators and other additional information obtained and reviewed by the government, including information on specific lots identified by Relators as being contaminated. The United States assessed the allegations and determined not to use its resources to pursue this

case. FDA has also taken into account Relators' claims in its regulatory oversight of Gilead, and taken actions it deemed appropriate. Relators' continued pursuit of the matter will necessarily entail the further expenditure of the government's resources. As is evident from the government's participation to date, the United States has actively monitored Relators' litigation. In particular, the government has found it necessary on multiple occasions to file briefs to set forth the United States' views on the interpretation and application of the FCA to the legal theories alleged by Relators and the challenges to it presented by defendants. Absent dismissal, the litigation will likely proceed to discovery, requiring the United States to commit even more significant resources to the case. Both parties may well file burdensome discovery and requests pursuant to *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951), for FDA and CMS documents and employee testimony. In particular, the parties likely will seek discovery about "exactly what the government knew and when." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2010). Following discovery, the same FDA and CMS employees relevant to discovery would be potential witnesses at any trial. This would divert those employees from their other duties and agency priorities.

Having already spent resources extensively investigating Relators' claims, reviewing the merits of the case as presented by Relators, and monitoring the case after declination, the United States has rationally concluded it is not in the public interest to spend further time and resources on Relators' litigation of this matter. Accordingly, the additional burdens that litigation of this case would impose on the United States present a rational basis for the government to seek dismissal under § 3730(c)(2)(A). The valid governmental purpose of conserving resources is undeniably furthered by and bears a rational relation to seeking dismissal. It is also appropriate for such a dismissal to occur now, to prevent any further dissipation of government resources.

Significantly, the Ninth Circuit found cost considerations such as those articulated here to be sufficient grounds for dismissal even if a case were meritorious. *Sequoia Orange*, 151 F.3d at 1146. It is thus not necessary under the *Sequoia* test to evaluate the potential "benefits" of a relator proceeding with his case. But even if it were, the government has made the rational determination that the costs of continued litigation will outweigh any benefit. Accordingly,

because the government has demonstrated a rational basis for dismissal of this action, and Relators cannot meet their burden, the Court should grant the United States' motion.

In addition to preserving scarce resources, dismissal is also appropriate to prevent Relators from undermining the considered decisions of FDA and CMS about how to address the conduct at issue here. FDA is authorized to withdraw an existing drug approval under specified circumstances, which generally require findings that the benefits of the drug no longer exceed the risks. *See* 21 U.S.C. § 355(e). If FDA proposes to withdraw approval, the drug's sponsor has substantial procedural rights, including a right to judicial review. *See id.*; 21 U.S.C. § 355(h); 21 C.F.R. § 314.200(g). Given the rigors of this process, and FDA's public-health obligation to avoid unnecessarily limiting patient access to safe and effective drugs, *see generally* 21 U.S.C. §§ 355(d), 355-1, 393(b), the agency typically seeks to address any issues through less disruptive mechanisms. *See* 21 U.S.C. §§ 355(e), 355(o)(3)-(4), 355-1; 21 C.F.R. § 201.57, 314.80(j).

In this case, FDA exercised continuing regulatory oversight of Gilead's manufacturing processes, including multiple on-site inspections of Gilead's facilities both before and after Relators filed their complaint. FDA took the actions that it deemed appropriate. Relators' case now asks a jury to find that different action was nevertheless required. The FCA was never intended to allow a relator to substitute his or her own judgment for that of the government as to whether the government received the benefit of its bargain.

V. NO EVIDENTIARY HEARING IS WARRANTED

At the recent case management conference, counsel for Relators suggested that they would insist on discovery from the government regarding the basis for its decision to dismiss this action. In *Sequoia Orange*, the Ninth Circuit acknowledged that a court need not reflexively schedule an evidentiary hearing when a motion to dismiss is filed, and it certainly did not suggest that a relator was entitled to discovery in such circumstances. To the contrary, the Ninth Circuit concluded that "[a] hearing is appropriate 'if the relator presents a colorable claim that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations, or that the Government's decision was based on arbitrary or

improper considerations.'" 151 F.3d at 1145 (quoting S. Rep. No. 99–345, at 26 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266); *see also Ridenour*, 397 F.3d at 931 (noting that hearings "are only to be granted if relators can show a 'substantial and particularized need for a hearing'") (quoting S. Rep. No. 99–345, at 26). Thus, neither an evidentiary hearing nor discovery is appropriate unless and until a relator comes forward with credible evidence to suggest that dismissal would be unreasonable, the government had not fully investigated, or the government's decision was based on arbitrary or improper considerations. *See United States ex rel. Mateski v. Mateski*, 634 F. App'x 192, 194 (9th Cir. 2015) ("The district court did not err in denying Mateski a hearing . . . ."). Here, Relators cannot proffer any evidence to make such a showing.

VI. CONCLUSION

The government moves to dismiss this action brought in its name for the legitimate purpose of conserving scarce resources that would need to be expended by the government to monitor this case and respond to pleadings, *Touhy* requests, and trial subpoenas. As the Relators cannot establish that this reason is arbitrary, capricious, fraudulent or illegal, the government's motion to dismiss should be granted.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

DAVID L. ANDERSON
United States Attorney

Dated: March 28, 2019

By: */s/*_____
SARA WINSLOW
Assistant United States Attorney

Dated: March 28, 2019

By: */s/ signature on file*_____
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[PROPOSED] ORDER

Having considered the United States' Motion to Dismiss pursuant to 31 U.S.C. § 3730(c)(2)(A), and any opposition, reply, and oral argument presented, the Court finds that the United States has identified a valid government purpose for dismissing the case, and shows a rational relationship between dismissal and accomplishment of the purpose. In addition, Relators have not demonstrated that dismissal is fraudulent, arbitrary and capricious, or illegal. *See United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). It is therefore HEREBY ORDERED that Relators' Second Amended Complaint is dismissed with prejudice. The Clerk shall close the file.

IT IS SO ORDERED

Dated:_____

_____
EDWARD M. CHEN
UNITED STATES DISTRICT JUDGE